DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 18 2000

Richard Landfield, Esq.
Michael J. Wilson, Esq.
Breed, Abbott & Morgan
1818 N Street, NW, Suite 600
Washington, D.C. 20036

Re: Docket No. 91P-0176/CP1

Dear Mr. Landfield and Mr. Wilson:

This letter is in response to the citizen petition, you filed with the Food and Drug Administration (FDA), under docket number 91P-0176/CP1, on behalf of the American National Red Cross, the American Association of Blood Banks, the American Blood Resources Association, and the Council of Community Blood Centers. In your petition you request that "the Commissioner of Food and Drugs issue a regulation or order, or take other appropriate action, to preempt state and local laws pertaining to the determination of donor suitability and to the testing and labeling of blood, blood components and blood derivatives."

You base your request upon the following grounds:

1. Overlapping or inconsistent state regulations that threaten the adequacy of the nation's blood supply;
2. Preemption of state and local laws pertaining to donor suitability and product labeling and testing is necessary to promote federal objectives; and
3. FDA's authority to preempt state and local law with respect to blood components and blood derivatives is well established.

On October 25, 1991, the Center for Biologics Evaluation and Research issued an interim response stating that additional time was needed to study the issues presented in your petition. In an attempt to gather additional evidence of the disruption to the blood supply you claim has occurred, FDA issued two Federal Register Notices, one published on August 27, 1993 (58 FR 45341), and the other on January 20, 1994 (59 FR 3117), asking for comment on your petition request. In the January 20, 1994, notice, FDA reopened the comment period in response to requests from the Association of Minority Health Professions Schools, several members of the hemophilia community and the general public, the National Hemophilia Foundation, the National Hemophilia Foundation/Northern Ohio Chapter, the Northwest Ohio Hemophilia Foundation, and several State health organizations. Those who requested the additional comment period cited the need for more time to determine the impact preemptive regulations would have on the blood

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product supply and the pending litigation arising from human immunodeficiency virus (HIV) and hepatitis contamination of the blood product supply in the early 1980's.

FDA has reviewed your petition and considered the arguments and evidence presented. We have also reviewed and considered the comments received in response to the two Federal Register Notices. Based on this review, FDA cannot grant the relief you request.

Sections 351 and 361 of the Public Health Service Act (PHS Act), as amended, 42 U.S.C. §§ 262 and 264, give the Commissioner the authority to regulate biological products, including blood and blood products, and to issue regulations to prevent the spread of communicable diseases. Blood and blood products are also regulated under the authority of the Federal Food, Drug, and Cosmetic (FD &C) Act, as amended, 21 U.S.C. 301-392. There is no express preemption provision in either the PHS Act or the FD & C Act. Under principles of implied preemption, however, FDA could, for example, preempt state and local law where a single uniform national standard was needed to protect the public health or where state law interferes with an important federal objective. Blanket preemption of all current laws governing the determination of donor suitability and the testing and labeling of blood, blood components, and blood derivatives would be a sizeable undertaking. Such an undertaking by the federal government is unwarranted unless there is evidence that the blood supply has actually been or is likely to be disrupted or there is a danger to public health and safety. You have not provided any specific cases or examples where the blood supply has actually been, or is likely to be, disrupted or halted due to what is characterized as overlapping or inconsistent state regulations.

Under Executive Order 13132, dated August 4, 1999, which went into effect on November 2, 1999, a federal agency may preempt State law by rulemaking when the exercise of State authority directly conflicts with the exercise of federal authority under a federal statute or when there is clear evidence to conclude that Congress intended the agency to have the authority to preempt State law.

Also, the Supreme Court, in Hillsborough County v. Automated Medical Laboratories, 471 U.S. 707 (1985), held that FDA may exercise the right to preempt local regulations if the regulations are overly restrictive and threaten the supply of blood products. In the Hillsborough case, which dealt with FDA preemption of local ordinances governing the collection of blood plasma, FDA took the position that states and localities were free to pass additional regulations to complement those implemented by FDA as long as they were not inconsistent with federal law.

Thus, while FDA has the ability to preempt state and local regulations governing the blood supply, as a matter of policy, such preemption is not appropriate in this case. While it is true that FDA's regulation of blood and blood products has become more active throughout the 1980's and into the 1990's, many states such as New York, New Jersey, California and Florida have regulatory programs in place. Where the states have developed blood programs and there is no

disruption in the blood supply or clear and present danger to public health, federal preemption is not warranted.

You contend that FDA is better equipped to comprehensively regulate the industry because states lack the expertise to regulate the blood supply. FDA disagrees with the assertion that states lack the expertise to regulate the blood supply. State legislatures have the authority to hold public hearings on proposed legislation and invite (or require) experts to provide their opinion on it. Where such hearings occur, blood organizations may participate in these hearings or comment on proposed legislation. In addition, most states have public health departments charged with developing regulations to enforce these statutes. New York, Florida, New Jersey, and California are examples of states with blood regulatory programs.

The petition suggests that because blood is a national resource, as demonstrated by the adoption in 1974 of a national blood policy, FDA should preempt all state regulations regarding the collection of blood and blood products in order to promote uniformity. FDA explicitly rejected this argument in Hillsborough. In Hillsborough, FDA took the position that despite comprehensive FDA regulations covering plasma collection and processing, states and localities were free to pass additional regulations as long as they were not inconsistent with federal law.

You base your request for preemption, in part, on the fact that FDA can regulate at a "state-of-the-art" level. You argue that FDA is a repository of knowledge with a wealth of resources and a variety of regulatory tools. Through these resources, you claim FDA is in a position to promulgate regulations, issue guidelines and recommendations, and approve amendments to licenses and changes in standard operating procedure (SOP) manuals in response to rapid changes in the blood industry. While FDA has provided detailed regulations and guidance in these areas, FDA would take steps to preempt only where there is a documented need for such action. The petition points to no evidence of specific, ongoing incidents that would prompt the agency to issue preemptive regulations in these areas.

FDA received two hundred and forty three comments on the petition. Comments were submitted by attorneys, blood banks, concerned/interested individuals, health care organizations, individuals with hemophilia, individuals with family members who have hemophilia but not HIV, groups and organizations representing hemophiliacs and those with HIV, physicians and health care providers, and four states. Most who commented were opposed to granting the petition. The commenters opposing the petition gave the following reasons why FDA should not preempt state and local law:

1. States have more comprehensive regulations that would be detrimentally affected by preemption;
2. Preemption would exempt the pharmaceutical companies from regulations and liability incurred during the 1980's; and
3. Preemption would unacceptably lower prevailing or existing standards.

Those who commented favorably on the petition cautioned that local power should not be totally usurped in order to allow state certification of testing laboratories and staff and the monitoring and inspection of laboratory operations. After a careful review of all of the arguments and evidence presented, FDA finds no basis for taking the actions proposed in your petition. FDA will, however, continue to monitor the various state and local regulations and will take any necessary steps to prevent actions that would interfere with the federal objective of a safe blood supply. In addition, FDA will continue to work cooperatively with the states in these areas.

Sincerely yours,

Margaret M. Dotzel
Associate Commissioner
for Policy